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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO-P-2013-0006]

RIN 0651-AC84

Revisions to Implement the Patent Term Adjustment Provisions of the Leahy-Smith America Invents Act Technical Corrections Act

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: Section 1(h) of the Act to correct and improve certain provisions of the Leahy-Smith America Invents Act and title 35, United States Code (AIA Technical Corrections Act) revised the patent law provisions pertaining to patent term adjustment. Section 1(h) of the AIA Technical Corrections Act revised the date from which the fourteen-month patent term adjustment period is measured, and clarified the date from which the three-year patent term adjustment period is measured, with respect to international applications filed under the Patent Cooperation Treaty. Under section 1(h) of the AIA Technical Corrections Act, the fourteen-month patent term adjustment period and the three-year patent term adjustment period is measured from the same date: the date

on which an application was filed under 35 U.S.C. 111(a) in an application under 35 U.S.C. 111; or the date of commencement of the national stage under 35 U.S.C. 371 in an international application. Section 1(h) of the AIA Technical Corrections Act also revised the provisions for notifying applicants of patent term adjustment determinations and revised the time period for requesting reconsideration and judicial review of the Office's patent term adjustment determinations and decisions. The United States Patent and Trademark Office (Office) published an interim rule on April 1, 2013 (patent term adjustment interim rule), amending the rules of practice to implement the changes to the patent term adjustment provisions in section 1(h) of the AIA Technical Corrections Act. This final rule adopts as final the amendments to the rules of practice originally set forth in the patent term adjustment interim rule. The Office is further providing an optional procedure for requesting a recalculation of patent term adjustment, as an alternative to the petition and fee otherwise required to request reconsideration of a patent term adjustment determination, for patents issued between January 14, 2013 (the date of enactment of the AIA Technical Corrections Act) and May 20, 2014 (patents issued on or after this date will have patent term adjustment determinations consistent with the AIA Technical Corrections Act) that resulted directly from international applications. The Office is providing this optional procedure for requesting a recalculation of patent term adjustment because the Office has experienced a significant delay in modifying the computer program used to calculate patent term adjustment with respect to the changes resulting from the AIA Technical Corrections Act.

DATES: Effective date: This final rule is effective on [Insert date of publication in the FEDERAL REGISTER]. The interim rule, published April 1, 2013, at 78 FR 19416, was effective on April 1, 2013.

Applicability date: The amendments to 37 CFR 1.702, 1.703, and 1.705 apply to any patent granted on or after January 14, 2013. The amendment to 37 CFR 1.704 applies to any application in which a notice of allowance was mailed on or after April 1, 2013.

The optional procedure for requesting a patent term adjustment recalculation applies only to patents issued between January 14, 2013, and May 20, 2014, that resulted directly from international applications, and the request must be filed no later than July 31, 2014.

FOR FURTHER INFORMATION CONTACT: Kery A. Fries, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, at (571) 272-7757.

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: Section 1(h) of the AIA Technical Corrections Act revised the patent term adjustment provisions of 35 U.S.C. 154(b). The AIA Technical Corrections Act revised the date from which the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i)(II), and clarified the date from which the three-year period in 35 U.S.C. 154(b)(1)(B), are measured with respect to international applications. Section 1(h) of the

AIA Technical Corrections Act also revised the provisions in 35 U.S.C. 154(b)(3) and (b)(4) for notifying applicants of patent term adjustment determinations and for requesting reconsideration and judicial review of the Office's patent term adjustment determinations and decisions.

Summary of Major Provisions: The Office published an interim rule on April 1, 2013, amending the rules of practice to implement the changes to the patent term adjustment provisions in section 1(h) of the AIA Technical Corrections Act.

This final rule specifically adopts as final the amendment to the rules of practice originally set forth in the patent term adjustment interim rule specifying that the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured from the date of commencement of the national stage under 35 U.S.C. 371 in an international application for consistency with the change to 35 U.S.C. 154(b)(1)(A)(i)(II) in section 1(h) of the AIA Technical Corrections Act. The change to 35 U.S.C. 154(b)(1)(B) did not require a change to the rules of practice, as the current rules of practice interpret the phrase "actual filing date of the application in the United States" in former 35 U.S.C. 154(b)(1)(B) as meaning the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

This final rule also adopts as final the amendment to the rules of practice originally set forth in the patent term adjustment interim rule relating to reconsideration of a patent term adjustment determination. This change provides that the two-month period for

requesting reconsideration of the patent term adjustment indicated on the patent may be extended by an additional five months, and thus permits a patentee to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted.

The Office is further providing an optional procedure for requesting a recalculation of patent term adjustment, as an alternative to the petition and fee otherwise required to request reconsideration of a patent term adjustment determination, for patents issued between January 14, 2013, and May 20, 2014, that resulted directly from international applications. The Office is providing this optional procedure for requesting a recalculation of patent term adjustment because the Office has experienced a significant delay in modifying the computer program used to calculate patent term adjustment with respect to the changes in the AIA Technical Corrections Act.

Costs and Benefits: This rulemaking is not economically significant under Executive Order 12866 (Sept. 30, 1993).

Background: The AIA Technical Corrections Act was enacted on January 14, 2013.

See Pub. L. 112-274, 126 Stat. 2456 (2013). Section 1(h) of the AIA Technical Corrections Act revised the patent term adjustment provisions of 35 U.S.C. 154(b). See 126 Stat. at 2457.

Section 1(h)(1)(A) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(1)(A)(i)(II) to change “the date on which an international application fulfilled the requirements of section 371” to “the date of commencement of the national stage under section 371 in an international application.” See id. Under former 35 U.S.C. 154(b)(1)(A)(i)(II), the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) was measured from “the date on which an international application fulfilled the requirements of section 371 of this title,” and an international application does not fulfill the requirements of 35 U.S.C. 371 until the applicant files (inter alia) the inventor’s oath or declaration (35 U.S.C. 371(c)(4) and MPEP § 1893.03(b)). See Changes to Implement the Inventor’s Oath or Declaration Provisions of the Leahy-Smith America Invents Act, 77 FR 48776, 48780 (Aug. 14, 2012). Thus, under section 1(h)(1)(A) of the AIA Technical Corrections Act, the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured from: (1) the date on which an application was filed under 35 U.S.C. 111(a); or (2) the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

Section 1(h)(1)(B) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(1)(B) to change “the actual filing date of the application in the United States” to “the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application.” See 126 Stat. at 2457. Thus, under section 1(h)(1)(B) of the AIA Technical Corrections Act, the three-year period in 35 U.S.C. 154(b)(1)(B) is measured from: (1) the actual filing date of the application

under 35 U.S.C. 111(a) in the United States; or (2) in the case of an international application, the date of commencement of the national stage under 35 U.S.C. 371 in the international application.

The change to 35 U.S.C. 154(b)(1)(A)(i)(II) required a modification in Office practice, as the date of commencement of the national stage under 35 U.S.C. 371 is not always the date on which an international application fulfilled the requirements of 35 U.S.C. 371. However, the change to 35 U.S.C. 154(b)(1)(B) did not require a modification in Office practice, because since the patent term adjustment provisions of 35 U.S.C. 154(b) were implemented in September 2000, the Office has interpreted the phrase “actual filing date of the application in the United States” in former 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56382-84 (Sept. 18, 2000) (explaining why the phrase “actual filing date of the application in the United States” in 35 U.S.C. 154(b)(1)(B) must mean the date the national stage commenced under 35 U.S.C. 371(b) or (f) in the case of an international application). The change to 35 U.S.C. 154(b)(1)(A)(i)(II) and (b)(1)(B) in section 1(h)(1) of the AIA Technical Corrections Act means that the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) and the three-year period in 35 U.S.C. 154(b)(1)(B) will be measured from the same date: (1) the date on which an application was filed under 35 U.S.C. 111(a) in an application under 35 U.S.C. 111; or (2) the date of commencement of the national stage under 35 U.S.C. 371 in an international application.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to change “shall transmit a notice of that [patent term adjustment] determination with the written notice of allowance of the application under section 151” to “shall transmit a notice of that [patent term adjustment] determination no later than the date of issuance of the patent.” See 126 Stat. at 2457. This change eliminated the need for the Office to provide an initial patent term adjustment determination with the notice of allowance and before the patent term adjustment under 35 U.S.C. 154(b)(1)(A)(iv) and 154(b)(1)(B) is known. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56374 (explaining that a two-part process is required because the Office is obliged under 35 U.S.C. 154(b)(3) to provide a patent term adjustment determination before the issue date and thus before the patent term adjustment is known).

Section 1(h)(3) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(4) to change “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the grant of the patent” to “[a]n applicant dissatisfied with the Director’s decision on the applicant’s request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director’s decision on the applicant’s request for reconsideration.” See 126 Stat. at 2457. This change to 35 U.S.C. 154(b)(4) clarified that: (1) a civil action under 35 U.S.C. 154(b)(4) is not an alternative to requesting reconsideration of a patent term adjustment under 35 U.S.C. 154(b)(3), but

instead is the remedy for an applicant who is dissatisfied with the Director's decision on the applicant's request for reconsideration; and (2) a civil action under 35 U.S.C. 154(b)(4) is the exclusive remedy for an applicant who is dissatisfied with the Director's decision on the applicant's request for reconsideration.

Section 1(n) of the AIA Technical Corrections Act provided that amendments made by the AIA Technical Corrections Act shall take effect on January 14, 2013 (the date of enactment of the AIA Technical Corrections Act), and shall apply to proceedings commenced on or after January 14, 2013. See 126 Stat. at 2459. Section 1(n) of the AIA Technical Corrections Act did not limit the applicability of the changes in section 1(h) to applications filed on or after January 14, 2013. Cf. Section 4405(a) of the American Inventors Protection Act of 1999 (AIPA), Pub. L. 106-113, 113 Stat. 1501, 1501A-552 through 1501A-591 (1999) (limiting the applicability of the patent term adjustment provisions of the AIPA to applications filed on or after May 29, 2000, the date that is six months after the date of enactment of the AIPA). Patent term adjustment proceedings are not "commenced" until the Office notifies the applicant of the Office's patent term adjustment under 35 U.S.C. 154(b)(3), which now occurs when the patent is granted. Therefore, the changes to 35 U.S.C. 154 in section 1(h) of section 1(n) of the AIA Technical Corrections Act apply to any patent granted on or after January 14, 2013.

Discussion of Specific Rules

The Office published an interim rule on April 1, 2013, revising §§ 1.702, 1.703, 1.704, and 1.705 to implement the changes to the patent term adjustment provisions in section 1(h) of the AIA Technical Corrections Act. See Revisions to Patent Term Adjustment, 78 FR 19416 (Apr. 1, 2013). This final rule adopts as final the amendments to §§ 1.702, 1.703, 1.704, and 1.705 originally set forth in the patent term adjustment interim rule. The following is a discussion of the amendments to Title 37 of the Code of Federal Regulations, Part 1, in the patent term adjustment interim rule.

Section 1.702: The patent term adjustment interim rule amended § 1.702(a)(1) to measure the fourteen-month period from the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application. With this amendment, § 1.702(a)(1)(i) states that a ground for potential patent term adjustment is the failure of the Office to: “Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application.”

The patent term adjustment interim rule amended § 1.702(b) to change the paragraph heading to “Three-year pendency.” No further change to § 1.702(b) was necessary, as the Office has interpreted the phrase “actual filing date of the application in the United States” in former 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application since the patent term adjustment

provisions of 35 U.S.C. 154(b) were implemented in September 2000 (as discussed previously).

Section 1.703: The patent term adjustment interim rule amended § 1.703(a)(1) to measure the fourteen-month period from the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application. With this amendment, § 1.703(a)(1)(i) states that the applicable time period is: “The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or the date the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.”

No change to § 1.703(b) was necessary, as the Office has interpreted the phrase “actual filing date of the application in the United States” in former 35 U.S.C. 154(b)(1)(B) as the date of commencement of the national stage under 35 U.S.C. 371 in an international application since the patent term adjustment provisions of 35 U.S.C. 154(b) were implemented in September 2000 (as discussed previously).

Section 1.704: The patent term adjustment interim rule amends § 1.704(c) to remove the reference to an application for patent term adjustment under § 1.705. With this amendment, § 1.705 no longer provides for a request for reconsideration of the patent

term adjustment indicated in the notice of allowance (as 35 U.S.C. 154(b)(3) no longer requires a patent term adjustment with the notice of allowance).

35 U.S.C. 154(b)(3)(C) (implemented in § 1.705(c)) provides for reinstatement of all or part of the period of adjustment reduced pursuant to 35 U.S.C. 154(b)(2)(C) if the applicant makes a showing “prior to the issuance of the patent” that, in spite of all due care, the applicant was unable to respond within the three-month period. Section 1.704(e) thus continues to provide that the submission of a request under § 1.705(c) for reinstatement of reduced patent term adjustment will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under § 1.704(c)(10).

Section 1.705: The patent term adjustment interim rule amended 1.705(a) to provide that the patent will include notification of any patent term adjustment under 35 U.S.C. 154(b). This change was due to the change to 35 U.S.C. 154(b)(3) to no longer require notice of a patent term adjustment with the notice of allowance. The Office plans to continue to provide an indication of the patent term adjustment with the issue notification, but the patent term adjustment under 35 U.S.C. 154(b) indicated on the patent is the “official” notification of the Office’s patent term adjustment determination. The Office will discontinue providing an indication of the patent term adjustment with the notice of allowance under 35 U.S.C. 151.

The patent term adjustment interim rule amended 1.705(b) to provide that the two-month period for requesting reconsideration of the patent term adjustment indicated on the patent may be extended by as many as five months under the provisions of § 1.136(a). This permits an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted. Section 1.705(b) no longer provides for a request for reconsideration of the Office's patent term adjustment determination prior to the grant of a patent.

The patent term adjustment interim rule amended § 1.705(c) to provide that any request for reinstatement of all or part of the period of adjustment reduced pursuant to § 1.704(b) for failing to reply to a rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must be filed prior to the issuance of the patent, and that this time period is not extendable. 35 U.S.C. 154(b)(3)(C) requires that such a showing be made "prior to the issuance of the patent," and thus the Office cannot permit the showing provided for in 35 U.S.C. 154(b)(3)(C) and § 1.705(c) to be submitted with a request for reconsideration of the Office's patent term adjustment determination under § 1.705(b).

The patent term adjustment interim rule removed the former provisions of §§ 1.705(d) and (e) in view of the changes to § 1.705(b).

Office Procedure for the Treatment of Requests for Reconsideration of Patent Term

Adjustment: The Office will conduct a manual redetermination of patent term adjustment in response to a request for reconsideration of the patent term adjustment. The Office makes the patent term adjustment determination indicated in the patent by a computer program that uses the information recorded in the Office's Patent Application Locating and Monitoring (PALM) system, except when an applicant requests reconsideration pursuant to § 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56370, 56380-81 (Sept. 18, 2000) (final rule). The PALM system was not originally designed for the purpose of calculating patent term adjustment as provided in 35 U.S.C. 154(b). The patent term adjustment provisions of 35 U.S.C. 154(b) are complex, with numerous types of communications exchanged between applicants and the Office during the patent application process. Thus, a manual redetermination of patent term adjustment could result in an amount of patent term adjustment that is the amount of patent term adjustment requested by the applicant, the same amount of patent term adjustment as indicated in the patent (i.e., there being no change), or a different amount of patent term adjustment that may be higher or lower than the patent term adjustment as indicated in the patent.

If the patent term adjustment redetermination results in the amount of patent term adjustment requested by the applicant, the Office will issue a decision granting the request for reconsideration and a certificate of correction indicating the revised patent term adjustment. If the patent term adjustment redetermination results in the same amount of patent term adjustment as indicated in the patent (i.e., there being no change)

and the Office does not require any additional information to render a decision on the request for reconsideration, the Office will issue a decision denying the request for reconsideration, and this decision is the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4).

If the patent term adjustment redetermination results in a different amount of patent term adjustment (higher or lower than the patent term adjustment indicated in the patent), the Office will issue a redetermination of patent term adjustment that explains how the Office arrived at the different amount of patent term adjustment. This redetermination of patent term adjustment is not the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4), but is simply a new patent term adjustment determination. If the Office issues such a redetermination of patent term adjustment in response to the request for reconsideration of the patent term adjustment, the applicant has two months from the date of the redetermination of patent term adjustment to file a renewed request for reconsideration of the patent term adjustment (no additional fee required) that addresses the issues included in the Office's redetermination of patent term adjustment. This two-month period is extendable under § 1.136(a).

If the patent term adjustment redetermination results in the same amount of patent term adjustment as indicated in the patent (i.e., there being no change) but the Office requires additional information to render a decision on the request for reconsideration of the patent term adjustment, the Office will issue a requirement for information to obtain the additional information. This requirement for information is not the Director's decision

on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4). If the Office issues a requirement for information in response to the request for reconsideration of the patent term adjustment, the applicant has two months from the date of the requirement for information to file a renewed request for reconsideration of the patent term adjustment supplying the required information (no additional fee required). This two-month period is extendable under § 1.136(a).

The Office will again conduct a redetermination of patent term adjustment in response to any renewed request for reconsideration in response to a redetermination of patent term adjustment or in response to a requirement for information. If this redetermination of patent term adjustment results in the amount of patent term adjustment requested by the applicant, the Office will issue a decision granting the request for reconsideration and a certificate of correction indicating the revised patent term adjustment. If this redetermination of patent term adjustment results in the same amount of patent term adjustment as indicated in the previous redetermination of patent term adjustment or in the patent, the Office will issue a decision denying the request for reconsideration (unless it is necessary to issue another redetermination of patent term adjustment or requirement for information) and a certificate of correction if necessary indicating the revised patent term adjustment as the result of a redetermination of patent term adjustment, and the decision denying the request for reconsideration is the Director's decision on the applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(4).

Optional Procedure For Seeking a Revised Patent Term Adjustment Calculation. As discussed previously, the Office makes patent term adjustment determinations by a computer program that uses the information recorded in the Office's PALM system, except when an applicant requests reconsideration pursuant to § 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56370, 56380-81 (Sept. 18, 2000) (final rule). The Office has experienced a significant delay in modifying the computer program used to calculate patent term adjustment with respect to measuring the fourteen-month patent term adjustment period from the date of commencement of the national stage under 35 U.S.C. 371 in international applications (the change to 35 U.S.C. 154(b)(1)(B) with respect to measuring the three-year patent term adjustment period from the date of commencement of the national stage under 35 U.S.C. 371 in international applications did not require a change to the computer program used to calculate patent term adjustment since the Office interpreted the phrase "actual filing date of the application in the United States" in former 35 U.S.C. 154(b)(1)(B) as meaning the date of commencement of the national stage under 35 U.S.C. 371 in an international application). This software modification was completed in April of 2014, and patent term adjustment determinations for patents issued on or after May 20, 2014, will be consistent with the changes to the patent term adjustment provisions in the AIA Technical Corrections Act.

Due to the significant delay in modifying the computer program the Office uses to calculate patent term adjustments with respect to this change in the AIA Technical Corrections Act, the Office is providing an optional procedure for patentees to request a

recalculation of their patent term adjustment without a fee as an alternative to the petition and fee otherwise required to request reconsideration of a patent term adjustment determination. The Office is specifically providing an optional procedure under which patentees seeking revised patent term adjustment calculations for patents issued between January 14, 2013, and May 20, 2014, that resulted directly from international applications (i.e., applications that have entered the national stage under 35 U.S.C. 371) may request that the Office recalculate the patent term adjustment without a request for reconsideration under § 1.705(b) or a fee. The procedure set forth in this final rule is not applicable to patents that resulted from applications under 35 U.S.C. 111(a), including bypass continuations of international applications or continuations of international applications that entered the national stage under 35 U.S.C. 371. Any request for recalculation of patent term adjustment under the procedure set forth in this final rule must be filed no later than July 31, 2014.

The Office is providing a Request for Recalculation of Patent Term Adjustment form (PTO/SB/132) for use in making such a request. The Request for Recalculation of Patent Term Adjustment form (PTO/SB/132) is available on the Office's Internet Web site at <http://www.uspto.gov/forms/index.jsp>. As discussed previously, this procedure and Request for Recalculation of Patent Term Adjustment form (PTO/SB/132) are applicable only for patents issued between January 14, 2013, and May 20, 2014, that resulted directly from an international application, and must be filed no later than July 31, 2014.

The fee specified in § 1.18(e) and any fee for a petition under § 1.136(a) required for a timely request for reconsideration under § 1.705 (§ 1.705(b)(1)) is not a fee paid by mistake or in excess of that required, and the Office may only refund fees paid by mistake or in excess of that required (35 U.S.C. 42(d)). Therefore, the procedure set forth in this final rule is **not** a basis for requesting a refund of the fee specified in § 1.18(e) or the fee necessary for any petition under § 1.136(a) for any request for reconsideration under § 1.705, including any previously filed request that was solely based on the Office's alleged error pertaining to the fourteen-month patent term adjustment period.

Applicants seeking a revised patent term adjustment in a patent issued after May 20, 2014, must file a request for reconsideration under § 1.705(b) that complies with the requirements of §§ 1.705(b)(1) and (b)(2) within two months of the date the patent issued.

To the extent that the procedures adopted under the authority of 35 U.S.C. 2(b)(2) and 154(b)(3) require that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and include the information required by § 1.705(b)(2) and the fee required by § 1.18(e), these requirements are hereby sua sponte waived for patents that meet all of the following criteria: (1) the patent issued between January 14, 2013, and May 20, 2014; (2) the patent resulted directly from an international application that has entered the national stage under 35 U.S.C. 371; and (3) the Request for Recalculation of the Patent Term Adjustment form (PTO/SB/132) is filed no later than July 31, 2014. See § 1.183. This

waiver does not apply to patents issued on or after May 20, 2014, and does not apply to requests that the Office recalculate the patent term adjustment for alleged errors other than those identified in this final rule.

A request for recalculation of patent term adjustment under the optional procedure to request a recalculation of patent term adjustment set forth in this final rule is not a request for reconsideration within the meaning of 35 U.S.C. 154(b)(3), and a recalculation of patent term adjustment under the optional procedure set forth in this final rule is not the Director's decision on an applicant's request for reconsideration within the meaning of 35 U.S.C. 154(b)(3) and (b)(4). Rather, a recalculation of patent term adjustment under the optional procedure set forth in this final rule is simply a new patent term adjustment determination under 35 U.S.C. 154(b)(3). Any request for reconsideration under 35 U.S.C. 154(b)(3) and § 1.705 of a new patent term adjustment determination done under the optional procedure set forth in this final rule must comply with the requirements of §§ 1.705(b)(1) and (b)(2) and be filed no later than two months from the date of the new patent term adjustment determination resulting from the recalculation of patent term adjustment. This two-month time period may be extended under the provisions of § 1.136(a).

Nothing in this final rule shall be construed as a waiver of the requirement of 35 U.S.C. 154(b)(4) that an applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the

Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration under 35 U.S.C. 154(b)(3)(B)(ii).

Recent Decision Concerning the Continued Examination Provision of 35 U.S.C.

154(b)(1)(B)(i): The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) recently decided that, with respect to the provisions of 35 U.S.C. 154(b)(1)(B)(i), that: (1) any time consumed by continued examination under 35 U.S.C. 132(b) is subtracted in determining the extent to which the period defined in 35 U.S.C. 154(b)(1)(B) exceeds three years, regardless of when the continued examination under 35 U.S.C. 132(b) was initiated; but (2) the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance is mailed, unless the Office actually resumes examination of the application after allowance. See Novartis AG v. Lee, 740 F.3d 593 (Fed. Cir. 2014). This decision in Novartis that the time consumed by continued examination under 35 U.S.C. 132(b) does not include the time after a notice of allowance, unless the Office actually resumes examination of the application after allowance, would require additional modifications of the patent term adjustment program. Such additional modifications of the patent term adjustment program were not included in the previously discussed modifications to the patent term adjustment program to make patent term adjustment determinations consistent with the changes to the patent term adjustment provisions in the AIA Technical Corrections Act that were recently completed. The Office has been holding requests for reconsideration of a patent term adjustment that raise issues pertaining to 35 U.S.C. 154(b)(1)(B)(i) pending the Federal Circuit decision in Novartis. The Office is now beginning to redetermine the patent term

adjustment manually for those patentees who have timely challenged their patent term adjustment determination.

The Office has adopted ad hoc procedures for seeking reconsideration of the patent term adjustment determination when there have been changes to the interpretation of the provisions of 35 U.S.C. 154(b) as a result of court decisions. See Interim Procedure for Patentees To Request a Recalculation of the Patent Term Adjustment To Comply With the Federal Circuit Decision in Wyeth v. Kappos Regarding the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A), 75 FR 5043, 5044 (Feb. 1, 2010). These ad hoc procedures were adopted because former 35 U.S.C. 154(b)(4) provided a time period for seeking judicial review that was not related to the filing of a request for reconsideration of the Office's patent term adjustment determination or the date of the Office's decision on any request for reconsideration of the Office's patent term adjustment determination. In view of the changes to 35 U.S.C. 154(b)(3) and 154(b)(4), and to permit additional time to determine whether to request reconsideration of the Office's patent term adjustment determination, the Office has provided in its interim and final rules in § 1.705(b) that its two-month time period may be extended under the provisions of § 1.136(a) (permitting an applicant to request reconsideration of the patent term adjustment indicated on the patent as late as seven months after the date the patent was granted). See Revisions to Patent Term Adjustment, 78 FR at 19418. Thus, the Office is not adopting ad hoc procedures for requesting a patent term adjustment recalculation specifically directed to the Federal Circuit decision in Novartis.

Comments and Responses to Comments: The Office received three written submissions containing comments from individuals in response to the patent term adjustment interim rule. The comments and the Office's responses to those comments follow:

Comment 1: Several comments requested clarification of the time period for seeking review of a patent term adjustment determination. One comment specifically requested clarification as to when a patentee may properly request reconsideration of a patent term adjustment determination on issues related to the three-month timeframe in 35 U.S.C. 154(b)(2)(C)(ii), other than a request for reinstatement under 35 U.S.C. 154(b)(3)(C) of an adjustment reduced under 35 U.S.C. 154(b)(2)(C) on the basis of a showing of all due care.

Response: For patents issued on or after January 14, 2013, any request for review or reconsideration of a patent term adjustment determination (whether or not pertaining to issues related to the three-month timeframe in 35 U.S.C. 154(b)(2)(C)(ii)) must be by way of an application for patent term adjustment under § 1.705(b) filed no later than two months from the date the patent was granted. This two-month period is extendable under the provisions of § 1.136(a).

35 U.S.C. 154(b)(3)(C) (and thus § 1.705(c)) continues to require that any request for reinstatement of all or part of the cumulative period of time of an adjustment reduced under 35 U.S.C. 154(b)(2)(C), on the basis of a showing that, in spite of all due care, the

applicant was unable to respond within the three-month period, must be filed prior to the issuance of the patent. Thus, where an applicant is seeking reinstatement under 35 U.S.C. 154(b)(3)(C) of patent term adjustment reduced under 35 U.S.C. 154(b)(2)(C), the showing required by 35 U.S.C. 154(b)(3)(C) must be filed prior to the issuance of the patent. However, where the patentee is not seeking reinstatement under 35 U.S.C. 154(b)(3)(C) of patent term adjustment reduced under 35 U.S.C. 154(b)(2)(C), but is simply contending that the Office's patent term adjustment determination is in error with respect to the three-month timeframe in 35 U.S.C. 154(b)(2)(C)(ii) (e.g., a reply is filed within the three-month timeframe in 35 U.S.C. 154(b)(2)(C)(ii), but the Office's patent term adjustment determination treats the reply as having been filed outside the three-month period in 35 U.S.C. 154(b)(2)(C)(ii)), any request for reconsideration or review of a patent term adjustment determination is by way of an application for patent term adjustment under § 1.705(b) filed no later than two months from the date the patent was granted (this two-month period being extendable under the provisions of § 1.136(a)).

Comment 2: One comment questioned whether § 1.7 applies to the time period for seeking review of a patent term adjustment determination under § 1.705(b).

Response: The Office treats the provisions of § 1.7 as applicable to the time for taking action to an application for patent term adjustment filed under § 1.705, since the time period set forth in § 1.705 is a time period for taking action in the Office within the meaning of 35 U.S.C. 21(b).

Comment 3: One comment stated that the language in section 1(n) of the AIA Technical Corrections Act concerning the effective date of the changes in section 1(h) means that a proceeding is commenced when patentee files the petition requesting reconsideration of the patent term adjustment rather than when the patent issues. The comment argued that the term “proceedings” refers to civil actions filed under 35 U.S.C. 154(b)(4)(A) rather than patent term adjustment general proceedings and opines that the term “proceedings” refers to any petition filed on or after the effective date rather than any patent granted on or after the effective date.

Response: As discussed in the patent term adjustment interim rule, the Office considers a patent term adjustment “proceeding” to be commenced when the Office makes a patent term adjustment and communicates that determination to the patentee (with the patent). A request for review of a patent term adjustment determination under § 1.705(b) is not the commencement of a new proceeding, but rather an action in a proceeding (the patent term adjustment determination) that had already been commenced by a patent term adjustment determination and communication of that determination to the patentee. In addition, the AIA Technical Corrections Act did not simply change the provisions for making and seeking review of patent term adjustment determinations, but additionally changed the provisions in 35 U.S.C. 154(b)(1)(A)(i)(II) and (b)(1)(B) pertaining to the period of patent term adjustment itself. It would be an anomalous situation for the changes to 35 U.S.C. 154(b)(1)(A)(i)(II) and (b)(1)(B) in the AIA Technical Corrections Act to be effective for a patent depending upon when and whether the patentee filed a request for review of a patent term adjustment determination under § 1.705(b), as under

the commenter's interpretation that the patent term adjustment itself could change simply by operation of a patentee seeking review or reconsideration of the Office's patent term adjustment determination.

Rulemaking Considerations:

A. Administrative Procedure Act (5 U.S.C. 553): This rulemaking relates to the rules of practice in patent cases to implement the changes to the patent term adjustment provisions of 35 U.S.C. 154(b) in the AIA Technical Corrections Act. This final rule simply adopts as final the revision of 37 CFR 1.702 and 1.703 originally set forth in the patent term adjustment interim rule for consistency with the changes to 35 U.S.C. 154(b)(1), and the revision of 37 CFR 1.704 and 1.705 also originally set forth in the patent term adjustment interim rule to extend the time period for seeking reconsideration of a patent term adjustment determination in light of the changes to 35 U.S.C. 154(b)(3). This final rule does not alter the substantive criteria of patentability or patent term adjustment. Therefore, these provisions involve rules of agency practice and procedure and/or interpretive rules. See *Bachow Commc'ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims); *National Whistleblower Ctr. v. Nuclear Regulatory Comm'n*, 208 F.3d 256, 262 (D.C. Cir. 2000) (rules that prescribe a timetable for asserting rights are procedural, unless they foreclose an effective opportunity to make

one's case on the merits) (quoting Lamoille Valley R.R. Co. v. ICC, 711 F.2d 295, 328 (D.C. Cir. 1983)); and Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive).

B. Regulatory Flexibility Act: For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes in this rulemaking will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This final rule adopts as final the: (1) revision of the date from which the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured in an international application for consistency with the change to 35 U.S.C. 154(b)(1)(A)(i)(II); and (2) extension of the time period for seeking reconsideration of the Office's patent term adjustment in view of the changes in 35 U.S.C. 154(b)(3) and (b)(4). These changes mirror the provisions in the AIA Technical Corrections Act and do not add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. For these reasons, the changes in this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the United States Patent and Trademark Office will submit a report containing this final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking will not result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. The rules of practice pertaining to patent term adjustment and extension have been reviewed and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0020. The changes in this rulemaking: (1) revise the date from which the fourteen-month period in 35 U.S.C. 154(b)(1)(A)(i) is measured in an international application for consistency with the change to 35 U.S.C. 154(b)(1)(A)(i)(II); and (2) revise (extend) the time period for seeking reconsideration of the Office's patent term adjustment in view of the changes in 35 U.S.C. 154(b)(3) and (b)(4). This rulemaking does not add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the changes in this rulemaking do not affect the information collection

requirements associated with the information collections approved under OMB control number 0651-0020 or any other information collections.

Notwithstanding any other provision of law, no person is required to respond to nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

For the reasons set forth in the preamble, the interim rule amending 37 CFR part 1 which was published at 78 FR 19416 on April 1, 2013, is adopted as a final rule without change.

Date: May 9, 2014

Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office

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